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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
PORTNER, V	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No. 09/155,982	Applicant(s) Klein
	Examiner Portner	Art Unit 1645

-- *The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 29, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *17-39* is/are pending in the application.

4a) Of the above, claim(s) *20, 21, 23, 25, 27, 32, 36, 38, and 39* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *17-19, 22, 24, 26, 28-30, and 33-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *17-39* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claims 17-39 are pending.

Claims 20-21, 23,25,27, 32,36,38-39 are drawn to a non-elected invention.

Claims 17-18, 19, 22,24,26,28-29, 30, 31,33-35 and 37 are under consideration.

Continued Prosecution Application

1. The request filed on June 29, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/155,982 is acceptable and a CPA has been established. An action on the CPA follows.

Priority

2. The renumbering of the claims defined in the Office action, previously sent, was to assist in clear communication. The elected invention remains the same. Applicant is requested to make note of how the claims have been renumbered so any communication with respect to the claims can be clearly understood. See 37 CFR 1.126.

Rejections Withdrawn

3. Claims 22 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Friedrich (1995) in light of Applicant's arguments.

Objections/Rejections Maintained

4. The objection to the disclosure because of the noted informality at page 24, line 11, for reasons of record in paper number 7, paragraph 12, a blank space is defined by [ ].

5. Claim 24 rejected under 35 U.S.C. § 112, first paragraph as failing to provide an enabling disclosure, for reasons of record in paper number 7, paragraph 16 and Response to arguments, in paper number 10, paragraph 14.

6. Claims 17-19, 22, 24, 26-29, 31, 30,33-35 and 37 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in **scope** with the instantly claimed invention, for reasons of record in paper number 7, paragraph 17 and response to arguments in paper number 10, paragraph 16, pages 6-7.

7. Claims 17,19, 26, 28 rejected under 35 U.S.C. 102(b) as being anticipated by Friedrich (1995), for reasons of record in paper number 7, paragraph "o", page 12, and response to arguments in paper number 10, paragraph 18.

8. Claims 17, 18, 19, 22, 24, 26, 28, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Akuzawa et al (1996) for reasons of record in paper number 7, paragraph 19 and Response to arguments, in paper number 10, paragraph 20. See attached English translation of the Japanese reference.

9. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich (1995) in view of Sugimoto et al (1988), for reasons of record in paper number 7, paragraph 21 and Response to Arguments, in paper number 10, paragraphs 22 and 23.

10. Claim 18 under 35 U.S.C. 103(a) as being unpatentable over Friedrich (1995) in view of Corbel et al (1982) for reasons of record in paper number 7, paragraph 22, and Response to Arguments, in paper number 10, paragraph 24.

11. Claims 17, 19, 22, 24, 26, 28-29, 31, 35 and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Tainturier et al (1981) in view of Friedrich (1995) and Harlow:Antibodies, A Laboratory Manual (1988,chapters 4,6,9, 14-15) for reasons of record in paper number 7, paragraph 23, and Response to Arguments, in paper number 10, paragraphs 26, and 27.

12. Claims 30, 33 and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Tainturier in view of Friedrich and Harlow further in view of Foster (US Pat. 4,444,879), for reasons of

record in paper number 7, paragraph 24, and Response to Arguments, in paper number 10, paragraph 28.

Claim Rejections - 35 U.S.C. § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 18, 19, 26 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

(Bd. App. 1949). In the present instance, **claim 18** recites the broad recitation "capable of recognizing", and the claim also recites "which do not exhibit a crossed reaction with an epitope" which is the narrower statement of the range/limitation. Claim 18 recites the phrase "capable of recognizing T.equigenitalis". The type of binding is not defined to be specific binding, and thus would encompass cross reactive binding and non-specific binding. Claim 18 depends from claim 17 which defines a specific type of binding and functional characteristics.

Claim 19 recites the phrase "the required monoclonal antibodies". This phrase lacks antecedent basis in the claim, which recites the term "monoclonal antibodies" that could be obtained by the recited process, but not limited to the process steps in the body of the claim. The product is not required to have any specific characteristics other than to be monoclonal antibodies. What characteristics are required to define the "required monoclonal antibodies" is not clearly pointed out.

Claim 26 recites the phrase "which may contain T.equigenitalis, into contact with an effective quantity of at least one monoclonal antibody or a fragment thereof". The amount is effective, but what it is effective for is not defined. The phrase "fragment thereof" could refer to T.equigenitalis or the monoclonal antibody. This portion of the rejection could be obviated by amending the claim to recite --Fv, Fab or F(ab')2--.

Claim 30 recites the ~~phases~~ phrases "reagents, for carrying out the intended immunologic reaction," and "optionally, reagents for blocking the non-antigen-antibody reactions.". The broad recitation of the ~~phase~~ phrase "reagents, for carrying out the intended immunologic reaction," would include reagents for blocking non-antigen-antibody reactions, because the immunological reaction would function specifically without non-specific reactions. If the reagents for carrying out the intended immunologic reaction, do not include reagents for blocking on-antigen-antibody reactions, what are they? The reagents are not clearly defined in the claim.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 17 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of monoclonal antibodies that specifically bind to T.equigenitalis and immunogenic compositions that comprise monoclonal antibodies, does not reasonably provide enablement for the use of any monoclonal antibody for prevention or treatment of infection and disease caused by T.equigenitalis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in **scope** with these claims.

The instant specification teaches how to make and use T.equigenitalis specific monoclonal antibodies, with various binding specificities and show the antibodies able to detect T.equigenitalis in a sample.

The antibodies of claim 17 are not so limited to any specific T.equigenitalis antigen, and may bind to any antigen produced by the pathogen, albeit intracellular, extracellular or surface expressed. The antigens are not defined to be virulence associated antigens for colonization, bacterial adherence factors, or essential antigens for survival of the pathogen. The monoclonals specifically bind to the antigens of T.equigenitalis, but are not defined to be opsonic antibodies. Dr. Fischer (1988) teaches that the opsonic character of immunoglobulin can vary (see page 528, paragraphs 3 and 4). While antibodies will bind to their respective antigens, all antibodies are not opsonic and therefore would not evidence a protective pharmaceutical effect.

No single epitope has been described as being an epitope to which a monoclonal antibody of the invention binds that provides a passive protective immune response. No pharmaceutical compositions have been described that contain at least one monoclonal antibody, in combination with a pharmaceutically inert carrier, that was shown to provide protection against pre-existing infection or to prevent future infections caused by T.equigenitalis.

The ability to reasonably predict the capacity of a single monoclonal that binds to a single bacterial epitope to induce protective immunity from in vitro antibody reactivity studies is problematic. Accordingly, it would require undue experimentation to formulate and use a

successful pharmaceutical composition of monoclonal antibodies without the prior demonstration of efficacy.

The specification fails to teach the identity any monoclonal antibodies or the epitope or epitopes the monoclonal antibodies must bind to induce a protective immune response, and thus function as a pharmaceutical composition. Further, the specification fails to provide an adequate written description of what surface proteins would induce monoclonal antibodies that could provide passive immune protection. The skilled artisan would be required to de novo locate, identify and characterize the protective epitopes to which the monoclonal antibodies must bind, or to screen single or combinations of various monoclonal antibodies in vivo for a protective effect. This would require undue experimentation given the fact that the specification is completely lacking in teachings of what binding characteristics the monoclonal antibodies must have in order to have a pharmaceutical effect.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 31, 2001

L. F. Smith

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9/5/01